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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,303	02/18/2004	Rafail Zubok	SPINE 3.0-455 CIPCONT VII	4832
530 7590 02/04/2009 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3775	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,303	Applicant(s) ZUBOK ET AL.	
	Examiner Nicholas Woodall	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-15 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by LeHuec (U.S. Publication 2003/0135213).

LeHuec discloses a device comprising a retaining clip (for example element 132) capable of being used with an intervertebral disc replacement device. The retaining clip includes a body member (central portion of the element) having a first side, a hook flange (elements 138 and 140), and two lateral flanges (142a and 143a). The hook flange extends from the body member in a first direction and is capable of clipping

Art Unit: 3775

retention of the first side of the body member against a flange of an intervertebral disc replacement device, wherein at least one surface (140) of the hook flange opposes and extends parallel to the first side of the body member. The lateral flanges extend from the body member in opposing second directions coplanar with the body member and perpendicular to the first direction, wherein the flanges are capable of being partially received over a portion of a bone screw in an intervertebral disc replacement device to prevent backing out of the bone screws. The body member further includes at least one attachment member (151) protruding from the first surface and capable of being in a snapping communication with at least one mounting hole of an intervertebral disc replacement device, wherein the mounting hole includes a substantially circular diameter corresponding with the rounded configuration of the attachment member.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeHuec (U.S. Publication 2003/0135213) in view of Powers (U.S. Publication 2005/0033430).

LeHuec discloses a device comprising an applicator (for example Figures 16a-16c of the reference) and at least one retaining clip (for example element 132). The retaining clip includes a body member (central portion of the element) having a first

Art Unit: 3775

side, a hook flange (elements 138 and 140), and two lateral flanges (142a and 143a).

The hook flange extends from the body member in a first direction and is capable of clipping retention of the first side of the body member against a flange of an intervertebral disc replacement device, wherein at least one surface (140) of the hook flange opposes and extends parallel to the first side of the body member. The lateral flanges extend from the body member in opposing second directions coplanar with the body member and perpendicular to the first direction. The application includes a first arm including a protruding member (814) secured to an opening in the body member of the retaining clip and a second arm including a protruding member (808) capable of being secured to an opening in the body member of a second retaining clip connected at a common bending elbow (812). The at least one retaining clip is removably secured to the first end of the first arm and the first end of the second arm. LeHuec fails to disclose the device further comprising an enclosure and a second retention clip. Powers teaches an enclosure capable of holding a set of sterilized surgical instruments that is made from a non-permeable material, such as plastic (page 2 paragraph 021), and the enclosure being sealed and devoid of substantially moist air by using a seal or cover that is removably attached to the enclosure (page 2 paragraph 023) in order to maintain the sterility of the surgical instruments until such a time as the instruments are to be assessed (page 2 paragraph 020). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of LeHuec further comprising an enclosure in view of Powers in order to maintain the sterility of the surgical instruments until such a time as the instruments are to be assessed. Regarding

Art Unit: 3775

the device further comprising a second retaining clip, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of LeHuec having a plurality of retaining clip, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Funatsu (U.S. Patent 5,269,790) in view of Blake III (U.S. Patent 4,296,751) and in view of Powers (U.S. Publication 2005/0033430).

Funatsu discloses a device comprising an applicator. The applicator includes a first arm (2) and a second arm (2'), wherein the arms extend in substantially the same direction from a common bending elbow (7 and 7'). The first ends of the arms are capable of being directly and removably engaged to retaining clips. Funatsu fails to disclose the device further comprising a first retaining clip, a second retaining clip, and an enclosure. Blake teaches a device comprising an applicator and further comprising a magazine system including a first retention clip (a first element 36) and a second retention clip (a second element 36), wherein the retaining clips directly engaged with the first ends of the applicator arms simultaneously (see Figure 11A), in order to provide an applicator having automatically advanced clips (column 1 lines 11-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Funatsu further comprising a magazine system in view of Blake in order to provide an applicator having automatically advanced clips. Regarding the device further comprising an enclosure, Powers teaches an enclosure capable of

Art Unit: 3775

holding a set of sterilized surgical instruments that is made from a non-permeable material, such as plastic (page 2 paragraph 021), and the enclosure being sealed and devoid of substantially moist air by using a seal or cover that is removably attached to the enclosure (page 2 paragraph 023) in order to maintain the sterility of the surgical instruments until such a time as the instruments are to be assessed (page 2 paragraph 020). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Funatsu further comprising an enclosure in view of Powers in order to maintain the sterility of the surgical instruments until such a time as the instruments are to be assessed.

Allowable Subject Matter

7. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection. The examiner has provided new grounds of rejection as necessitated by the amendment.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Art Unit: 3775

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733